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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/933,267 | 08/21/2001 | Francis Kalush | CL000258CI4 | 5274 |

25748 7590 12/20/2004

CELERA GENOMICS CORP.
ATTN: WAYNE MONTGOMERY, VICE PRES, INTEL PROPERTY
45 WEST GUDE DRIVE
C2-4#20
ROCKVILLE, MD 20850

EXAMINER

STANDLEY, STEVEN H

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1646

DATE MAILED: 12/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|--------------------|---------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 09/933,267 | KALUSH ET AL. | |
| | Examiner | Art Unit | |
| | Steven H. Standley | 1646 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 January 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 18-35 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 18, 19, 24-29, 32 and 33 is/are allowed.
- 6) ☒ Claim(s) 20-23, 30, 31, 34 and 35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>1/05/04</u> . | 6) <input checked="" type="checkbox"/> Other: <u>892 references</u> . |

DETAILED ACTION

Sequence Compliance

1. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and /or amino acid sequences set forth in 37 CFR 1821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 because 37 CFR 1.821 (a)(2)(c-d) states that each sequence disclosed must appear separately in the sequence listing and in the text of the description and claims whenever described. For example, the appropriate SEQ ID NO must be recited in Figure 1 on page 16. See MPEP 2422 & 2431. Applicant must comply with the requirements of the sequence rules (37 CFR 1.821-1.825) before the application can be examined under 35 U.S.C. § 131 and 132. Note that failure to respond to both the requirements for sequence compliance and the rejections below will be held as nonresponsive, and may result in abandonment of this application.

Election/Restrictions

2. Applicant's election without traverse of Group III (claims 4-11, and 15) in the reply filed on 01/05/04 is acknowledged. It is acknowledged that the newly submitted claims, filed on 01/05/04, are drawn to the subject matter of claims 4 and 5 of the elected Group III. Furthermore, the cancellation of original claims 1-17 is acknowledged.

Claim Objections

3. Claims 28-35 are objected to because of the following informalities: They contain reference to 'SNP' without first disclosing the meaning of the acronym. In order to make the description of the invention more clear, the first claim that mentions 'SNP' should fully express the phrase, and be followed by parentheses, which identify the acronym to be used in the following claims. Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 22-23 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

No written description is provided in the instant specification as to what structurally constitutes nucleotide sequences "...comprising nucleotides 306168-306503 of SEQ ID NO: 1", the boundaries and functional elements of which would be unknown to one skilled in the art at the time the invention was made. The specification has not described, nor can it be reasonably visualized by one skilled in the art, the structural and functional elements attributable to chromosome 6, which represents the boundaries

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of the nucleotide sequences as currently claimed. For example, chromosome 6 contains other undescribed promoters, coding regions, 5' and 3' flanking regions, exons and introns, each with ^{their} ~~there~~ own unique structure and function that is not described in the instant specification.

It is suggested that amending claims 22-23 to read "An isolated cDNA or transcript molecule consisting of a nucleotide sequence selected from the group" might obviate this rejection.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 20, 30 and 34 are rejected under 35 U.S.C. 102(b) as being anticipated by Gossan (US patent number 5464758, Nov. 7, 1995, SEQ ID NO: 16, figure 10, column 5).

Gossan teaches a polynucleotide and its complementary sequence wherein the polynucleotide sequence comprises 20 contiguous nucleotides of SEQ ID NO: 01 wherein the 20 nucleotides include position 306382 of SEQ ID NO: 01; thereby meeting the structural limitations of an 'SNP detection reagent' such as a 'probe, primer, or an allele-specific probe and primer (i.e., as it relates to claims 30 and 34).

6. Claims 21, 31, and 35 are rejected under 35 U.S.C. 102(b) as being anticipated by Strausberg (GenBank Accession AI073549; EST name ov45e08.x1; Clone id IMAGE 1640294; Aug. 6, 1998).

Strausberg teaches a polynucleotide and its complementary sequence wherein the polynucleotide sequence comprises 20 contiguous nucleotides of SEQ ID NO: 01 wherein the 20 nucleotides include position 306382 of SEQ ID NO: 01, and further wherein position 306382 of SEQ ID NO: 01 is 'G;' thereby meeting the structural limitations of an 'SNP detection reagent' such as a 'probe, primer, or an allele-specific probe and primer (i.e., as it relates to claims 31 and 35).

It is noted that this rejection is based upon a disclosure provided in a computer database record. Because the database was indexed so as to be available to the relevant part of the public, it is considered to be a U.S.C. § 102; see *In re Wyer*, 210 USPQ 790.

7. Claim 22 is rejected under 35 U.S.C. 102(b) as being anticipated by Shine (WO 87/05049, Aug. 27 1987, Figure 1, page 19).

Shine teaches a polynucleotide and its complementary sequence that shares 100% identity with the fragment of SEQ ID NO: 01 comprising the contiguous nucleotides from position 306168 to position 306503.

8. Claim 23 is rejected under 35 U.S.C. 102(b) as being anticipated by Strausberg (GenBank Acc# AI073549; EST name ov45e08.x1; Clone id IMAGE 1640294; Aug. 6, 1998).

Strausberg teaches a polynucleotide and its complementary sequence that shares 100% identity with the fragment of SEQ ID NO: 01 comprising the contiguous nucleotides from position 306168 to position 306503 wherein the nucleotide at position 306382 is 'G.'

It is noted that this rejection is based upon a disclosure provided in a computer database record. Because the database was indexed so as to be available to the relevant part of the public, it is considered to be a U.S.C. § 102; see *In re Wyer*, 210 USPQ 790.

Allowable Subject Matter

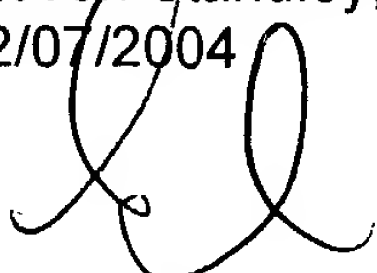
9. Claims 18-19, 24-29, and 32-33 are allowed.

Summary

Any inquiry concerning this communication should be directed toward examiner Steven Standley (Ph: 571-272-3432). The examiner can normally be reached Monday through Friday from 8:00 AM to 4:30 PM. If attempts to reach the Steven Standley fail, the examiners' supervisor, Brenda Brumback, can be reached at (571 272-0961).

Information regarding the status of an application may be obtained from the Patent Application Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at (toll free) 866-217-9197.

Steven Standley, Ph.D.
12/07/2004



ROBERT C. HAYES, PH.D.
PATENT EXAMINER